

A

Docket Number	CL/V-31174A
---------------	-------------

**FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10**

EL661308936US  
Express Mail Label Number

October 13, 2000  
Date of Deposit

1c921 U.S. PTO

09/687278

10/13/00

Address to: Assistant Commissioner for Patents  
Box Patent Application  
Washington, DC 20231

## UTILITY PATENT APPLICATION TRANSMITTAL AND FEE SHEET

Transmitted herewith for filing under 37 CFR §1.53(b) is the utility patent application of

Applicant (or identifier): AJELLO ET AL.

Title: DEBLOCKING CONTACT LENSES

Enclosed are:

1. ☒ Specification (Including Claims and Abstract) - 21 pages
2. ☒ Drawings - 2 sheets
3. ☒ Executed Declaration and Power of Attorney (original or copy)
4. ☐ Microfiche Computer Program (appendix)
5. ☐ Nucleotide and/or Amino Acid Sequence Submission
- ☐ Computer Readable Copy
- ☐ Paper Copy
- ☐ Statement Verifying Identity of Above Copies
6. ☐ Preliminary Amendment
7. ☐ Assignment Papers (Cover Sheet & Document(s))
8. ☐ English Translation of
9. ☐ Information Disclosure Statement
10. ☐ Certified Copy of Priority Document(s)
11. ☒ Return Receipt Postcard
12. ☐ Other:

**Filing fee calculation:**

- ☐ Before calculating the filing fee, please enter the enclosed Preliminary Amendment.  
☐ Before calculating the filing fee, please cancel claims .

Basic Filing Fee								\$ 710
Multiple Dependent Claim Fee (\$ 270)								\$
Foreign Language Surcharge (\$ 130)								\$
	For	Number Filed		Number Extra		Rate		
Extra Claims	Total Claims	42	-20	22	x	\$ 18	=	\$ 396
	Independent Claims	9	-3	6	x	\$ 80	=	\$ 480
TOTAL FILING FEE								\$ 1,586

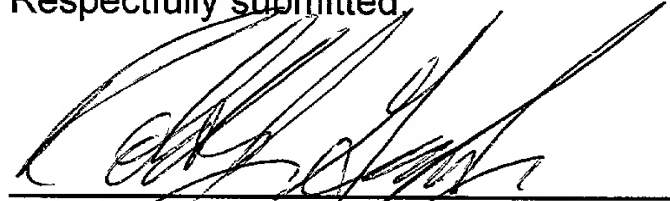
- ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis Corporation in the amount of \$1,586. An additional copy of this paper is enclosed. The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16 and §1.17 which may be required in connection with this application, or credit any overpayment, to Deposit Account No. 19-0134 in the name of Novartis Corporation.
- ☒ Applicants hereby claim priority to the provisional application having a priority date of 10/27/99 which application is being converted to a provisional application by petition which is being filed concurrently on 10/13/00 based on nonprovisional Application Serial No. 09/428,067 filed on 10/27/99.

Please address all correspondence to the address associated with Customer No. 001095, which is currently:

Thomas Hoxie  
Novartis Corporation  
Patent and Trademark Dept.  
564 Morris Avenue  
Summit, NJ 07901-1027

Please direct all telephone calls to the undersigned at the number given below, and all telefaxes to (678) 415-3068.

Respectfully submitted,



Robert J. Gorman, Jr.  
Attorney for Applicants  
Reg. No. 41,789  
Tel. No. (678) 415-4389

Date: October 13, 2000

## DEBLOCKING CONTACT LENSES

### FIELD OF THE INVENTION

5           The invention relates to a method for use in manufacturing ophthalmic components, such as a contact lens. Specifically, the invention relates to a method and apparatus for removing a contact lens from a mold, a process also known as “debblocking” a contact lens.

### BACKGROUND OF THE INVENTION

10           The most common materials currently utilized in manufacturing soft contact lens are polymers and copolymers of 2-hydroxyethyl methacrylate (HEMA). These hydrophilic polymers move well on the eye and provide sufficient oxygen permeability for daily wear. Some HEMA soft contact lenses have been approved for extended periods of wear up to 7 days. However, such extended wear may result in corneal swelling and development of surface blood vessels in the sclera.

15           Research for improved oxygen permeable polymers has led to the development of polymers containing silicone groups. A variety of siloxane-containing polymers exhibit high oxygen permeability. Because of their oxygen permeability siloxane-containing polymers show great promise as the next generation of contact lens polymer. Unfortunately, siloxane-containing polymers possess physical characteristics that have thus far hindered their  
20           ascension to dominance in the field of contact lenses.

          In layman’s terms, siloxane-containing polymers are sticky. Contact lenses made of these polymers are hydrophobic and tend to adhere to various surfaces, severely complicating the manufacturing process. For example, a siloxane-containing lens will adhere to surfaces during the transfer of the lens from point to point during the  
25           manufacturing process. One particular point in the manufacturing process that often causes problems is removing the lens from the mold, a step that is also known as “debblocking” the lens.

          Those familiar with the art know that a contact lens mold typically consists of a base curve (convex) mold half and a front curve (concave) mold half formed from a  
30           polymer. In the siloxane-containing lens manufacturing context, polyolefin (e.g., polypropylene) molds are most commonly used. The front curve and base curve mold

halves are fitted together to form a small crescent shaped mold cavity between the base curve mold half and the front curve mold half. Introducing a fluid monomer to the front curve mold and then sandwiching the monomer with the base curve mold forms a fluid monomer in the shape of a lens. The choice of monomer and the shape of the crescent shaped cavity determine the optical properties of the lens. The monomer is then polymerized through heat treatment, light treatment or other polymerizing process, thus forming a soft contact lens.

After the lens is formed the mold halves are separated. Contact lenses, especially siloxane-containing lenses, regularly stick to one of the mold halves. In the siloxane-containing lens context, the lenses tend to attach to the front curve mold half. Those skilled in the art typically refer to a front curve or back curve mold half as a "mold." For the rest of this discussion the terms mold half and mold will be used interchangeably unless the context requires otherwise. Those skilled in the art will readily recognize such context.

The reason for the particular attachment to the front curve mold is not completely understood. The adherence of the lens is probably related to a combination of the lens mold interface phenomena and physical properties of the lens including the mold surface morphology, internal stress build up within the lens (or distortion) and the stress distribution and the wettability of the lens material.

Under dry conditions it is difficult to separate a siloxane-containing lens from a mold surface due to adhesion between the lens and mold surface. Lenses can be forced to separate from the mold surface by applying a force, such as with a pair of tweezers. Nevertheless, the application of such force to peel a lens off of a mold surface often results in damage to the lens. For example, the lens may become scratched, distorted or torn, each of which renders it useless.

The adhesion between the lens and mold surface can be weakened when the molecules of the lens polymer become mobile. For example, the molecules may become mobile by adding heat or chemicals such as a solvent. Accordingly, an alternative method for removing a lens from a mold surface involves the use of a solvent such as isopropyl alcohol ("IPA"). In this method IPA is applied directly to the lens as it adheres

to the mold surface. The solvent swells the lens and helps reduce the forces holding the lens to the mold surface. The lens may then be removed from the mold surface.

Although this method of deblocking reduces the likelihood of damage to the lens, the collection and disposal of used solvent carries both an economic and environmental price. For example, used IPA may be classified as hazardous waste in some states. Accordingly, a need exists for an improved method for removing a contact lens from a mold.

### **OBJECT AND SUMMARY OF THE INVENTION**

An object of the invention is to provide a non-mechanical method of deblocking a contact lens.

A further object of the invention is to provide a method of deblocking a contact lens that does not require a solvent.

A further object of the invention is to provide a method of deblocking a contact lens that does not damage the contact lens.

A further object of the invention is to provide a method of deblocking a contact lens that does not generate a potentially hazardous waste as a by-product.

A further object of the invention is to provide a method of deblocking a contact lens using a cryogenic material.

An object of the invention is to provide an apparatus for use in deblocking a contact lens.

A further object of the invention is to provide an apparatus for use in deblocking a contact lens that may be used in a cryogenic deblocking process.

A further object of the invention is to provide an apparatus for use in deblocking a contact lens that does not damage the contact lens.

A further object of the invention is to provide an apparatus for use in deblocking a contact lens that allows substantial automation of a cryogenic deblocking process.

A further object of the invention is to provide a carrier that can receive a contact lens mold bearing a contact lens and transport said mold and lens through a deblocking sequence in an efficient manner.

The invention meets these objects with a method for extracting a contact lens from a mold by lowering the temperature of the contact lens to a temperature sufficient to lessen

adherence between the lens and the mold then removing the lens from the mold. The lowering of the temperature of the contact lens is accomplished by direct or indirect contact with a cryogenic substance, such as liquid nitrogen.

The invention also meets these objects with an apparatus to deblock and collect  
 5 contact lenses comprising a top plate for receiving a contact lens mold bearing a contact lens and a bottom plate for receiving the contact lens. The contact lens mold is oriented within the top plate such that the contact lens is free to fall to the bottom plate after deblocking through application of a cryogenic material. The following sections set forth a preferred embodiment of the invention in which:

### 10 BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a cross-sectional view of a contact lens mold.

FIG. 2 is a perspective view of one embodiment of the deblocking apparatus according to the invention with a corner section removed.

FIG. 3 is a cross-sectional view of the apparatus section removed from FIG. 2.

15 FIG. 4 is a perspective view of the apparatus section shown in FIG. 3.

FIG. 5 is a cross-sectional view of a deblocked contact lens on a contact lens holder.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is based upon the surprising discovery that reducing the temperature of a contact lens may weaken the forces causing adherence of the contact lens,  
 20 and specifically a siloxane-containing lens, to the surface of a mold.

The present invention is a method for extracting a polymeric contact lens from a mold. In its broadest aspects, the method comprises lowering the temperature of the contact lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens, and thereafter removing the  
 25 lens from the mold.

Although the inventors do not wish to be bound by any particular theory, it appears that the step of lowering the temperature of the contact lens substantially reduces the molecular mobility of the contact lens polymer. Depending upon the circumstances, the step of lowering the temperature of the contact lens can comprise directly contacting  
 30 the contact lens with the cryogenic substance, or contacting the mold with a cryogenic substance while the lens is in contact with the mold.

In particular, the cryogenic substance can be anything which, when placed in contact with either the mold or the lens, will reduce the temperature to the desired degree. The cryogenic substance is preferably selected from the group consisting of liquid nitrogen, liquid helium, liquid carbon dioxide, and solid carbon dioxide ("dry ice"), with liquid nitrogen being most presently preferred as having the optimum combination of ease of use and economic availability.

As noted above, the method is particularly useful when the contact lens material is a siloxane-containing polymer, more particularly a siloxane-containing hydrogel polymer.

In another aspect, the method comprises bringing the contact lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens. Thereafter, the method comprises separating the lens from the mold, and recovering the separated lens. Preferably, the step of separating the lens from the mold comprises lowering the temperature of the lens to a temperature at which the lens will release from the mold without the application of external force to the lens. As in the previous embodiment, the method can comprise either bringing the lens into contact with the cryogenic substance, or it can comprise bringing the mold with the lens therein or thereon into contact with the cryogenic substance, with the cooling of the mold being sufficient to cool the lens to the point at which it will release as desired from the mold.

In another aspect, the invention comprises a method for extracting a silicon containing polymeric contact lens from a mold comprising the steps of orienting a contact lens bearing mold upon a carrier with the contact lens in a position to fall from the mold under the influence of gravity. A contact lens collector is then positioned or situated in a position at which it can collect a contact lens that may fall from the oriented carrier. The mold carrying the lens is then brought into contact with the cryogenic substance which, as noted previously, causes the lens to release from the mold and separate therefrom. The method also comprises collecting the lens following its separation from mold.

In another aspect, the invention comprises a method for manufacturing silicon containing polymeric contact lenses. In this embodiment, the method comprises bringing

two mold halves together to form a lens mold; filling the mold with an uncured polymer (those familiar with polymer chemistry will recognize that this can also be a pre-polymer or a low molecular weight polymer, or a polymer that can be further cross-linked); curing the polymer in the mold, usually by application of heat or ultraviolet light depending upon the particular chemistry of the lens polymer; separating the mold halves from one another; and bringing the mold half bearing the contact lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold half to a point at which removing the lens will not damage the lens. Thereafter the method comprises separating the lens from the mold half and recovering the separated lens.

When a siloxane-containing lens attached to a polypropylene mold is placed in a vessel containing a quantity of liquid nitrogen the lens separates itself from the mold and falls to the bottom of the vessel after a very short period of time and the polypropylene mold floats to the top of the liquid nitrogen.

Upon warming, the lens releases any liquid nitrogen adhering to its surface by giving off gaseous  $N_2$ . Any liquid nitrogen remaining in the container likewise evaporates. The end result is a clean deblocked contact lens without any troublesome waste byproducts, e.g. used IPA.

At this time, the physical mechanism of the cryogenic deblocking method is not completely understood. The fact that a lens will peel itself off of a mold surface suggests that there is some negative force or environment created by lowering the temperature of the contact lens which assists in reducing adhesion at the interface. For example, it is speculated that there may be a very small physical dimensional change in the lens and mold surface that causes the lens to release.

The operation of the preferred embodiment of the apparatus of the present invention comprises forming a contact lens in a mold, separating the mold and placing the mold half bearing the contact lens within a carrier with the mold being oriented contact lens side down. Situated underneath the mold and directly beneath the contact lens is a contact lens collector, a structure designed to receive the contact lens. Liquid nitrogen is then applied to the side of the mold opposite the contact lens in an amount sufficient to lower the temperature of the contact lens to the point where it would automatically release from the



mold and fall to the contact lens collector. The thus deblocked contact lens then proceeds to subsequent steps in the manufacturing process.

The temperature sufficient to lower the temperature of the contact lens to the point where it would automatically release from the mold cannot be precisely defined as it will depend the cryogenic material used, as well as the materials used for the lenses and for the molds. One of skill in the art will recognize that determination of a sufficient temperature is easily obtained by only routine experimentation once the materials are known. Typically, the temperature achieved with liquid nitrogen is sufficient to deblock commercially available lens materials from a polypropylene mold. However, some mold materials may be incompatible with the present method. For instance, the method disclosed herein is may not be operable with molds made of certain grades of polycarbonate.

Referring now to FIG. 1, a cross-section of a typical soft contact lens mold 10 comprising a base curve mold half 12 and a front curve mold half 14 is shown. As can be seen from FIG. 1, the base curve mold half 12 and the front curve mold half 14 fit together to form a crescent shaped cavity. As discussed previously, placing a monomer in the crescent shaped cavity and polymerizing the monomer forms a contact lens 16. Typically, an excess of monomer is used to ensure a fully formed lens. Excess monomer results in a portion of the monomer being squeezed out of the mold. The excess monomer is separated from the contact lens 16 and retained within the overfill well 11 formed by the compression of the front curve critical lip 9 to the base curve seal 8.

After the contact lens 16 is formed the mold is separated into its two halves. Typically the contact lens adheres to the front curve mold.

In another aspect the invention is an apparatus for deblocking and collecting contact lenses formed of hydrophilic polymers that tend to adhere to mold surfaces. In this aspect the invention comprises a contact lens mold and means, illustrated in the drawings as the reservoir 13, for cooling the contact lens mold 14 and the lens 16 that is adhered to the mold 14. Although a front curve lens mold or a base curve lens mold may be utilized in the invention, for purposes of this discussion it will be assumed that the lens mold is a front curve lens mold 14. The means for cooling cools the mold 14 and the lens 16 to a temperature at which the lens 16 may be removed from the mold without damaging the lens may encompass any known method for cooling such as placing the contact lens and the

mold to which it adheres within a sufficiently cooled enclosure. Such an approach, however, is cumbersome and inefficient and does not lend itself to integration in an automated manufacturing process.

A preferred embodiment of the invention is illustrated in FIG. 2 wherein the lens mold **14** is retained by a top plate **20**. The top plate **20** is situated above the bottom plate **22**. The bottom plate **22** is substantially parallel to the top plate **20** and retains a lens collector **26**. The top plate **20** and the bottom plate **22** are aligned so that the lens mold **14** and the lens **16** are in axial alignment with the lens collector **26** retained by the bottom plate **22**.

The side of the lens mold **14** opposite the lens **16** is formed to create a reservoir **13**. A cryogenic material ("cryogen") is introduced to the reservoir **13** (preferably at its center) thereby cooling the mold **14** and the lens **16** to a temperature sufficient for the lens **16** to release from the mold **14** and fall to the lens collector **26**. The cryogenic cooling of the mold also has the effect of shrinking the overfill well **11** thereby effectively trapping the excess monomer and removing it from the process. The cryogenic substance is preferably selected from the group consisting of liquid nitrogen, liquid helium, liquid carbon dioxide, and solid carbon dioxide ("dry ice"), with liquid nitrogen being most presently preferred as having the optimum combination of ease of use and economic availability.

Referring now to FIG. 3, another embodiment of the invention is a contact lens carrier **18**. The contact lens carrier according to the invention comprises two plates: a top plate **20** and a bottom plate **22**.

The top plate **20** is defined by a top surface **19** and a bottom surface **21** separated by a predetermined width. The top plate **20** also possesses a plurality of holes **24**, in this instance twelve, for receiving molds **14** bearing contact lenses **16**. The contact lens mold received by the top plate **20** will be a front curve lens mold in most instances. Top plate **20** can also receive back curve lens molds with appropriate modifications. FIG. 3 shows a mold **14** oriented within the top plate hole **24** to place the contact lens **16** at a location intermediate the top plate top surface **19** and the top plate bottom surface **21**. This orientation suspends the contact lens **28** above the bottom plate **22**.

The top plate **20** also includes a retaining device to secure the positioning of the molds **14** during the deblocking process and during subsequent downstream manufacturing processes. Any suitable retaining device may be used to secure the positioning of the molds

**14.** For example, a retaining plate having holes corresponding to the top plate holes **24** may be placed above the molds. Likewise, the perimeter of the top plate holes **24** and the molds **14** may be molded or machined such that the molds **14** “snap-fit” into place.

FIG. 3 and FIG. 4 show a preferred embodiment of such a retaining device comprising a flexible tab **30** having a notch **32** that receives the outer flange **15** of the mold **14**. A pair of flexible tabs **30** may retain each mold **14**. Alternatively, the molds **14** may be oriented such that the outer flange **15** of one mold overlaps the outer flange **15** of another mold thereby reducing the number of flexible tabs **30** required to effectively secure the positioning of the molds. The molds **14** in FIG. 3 and FIG. 4 are secured by such an overlapping arrangement.

In some instances the contact lens may not separate itself from the mold. In these instances an application of a slight external force, such as tapping the mold, should suffice to dislodge the lens. The tapping force may be applied manually as with a small mallet. Alternatively, the tapping force may be automated. For example a small spring loaded piston may be placed in contact with the mold and automatically triggered thereby sending a small shockwave through the mold.

During deblocking, liquid nitrogen is applied to the side of the mold **14** opposite the contact lens **16** as shown in FIG. 3. The liquid nitrogen substantially reduces the temperature of the mold **14** and the contact lens **16**. The contact lens **16** separates itself from the mold **14** and falls toward the bottom plate **22**. The small quantity of liquid nitrogen applied to the mold **14** quickly evaporates leaving behind only a clean and deblocked lens mold.

In the preferred embodiment shown in FIG. 3, the top plate **20** and the bottom plate **22** are attached by a set of locking pins **17** that are received by both the top plate **20** and the bottom plate **22**. Preferably a distance separates the top and bottom plates. In the preferred embodiment shown in FIG. 3, washer-like spacers **23** retained by the locking pins **17** separate the top plate **20** and the bottom plate **22**. Alternatively, the spacers may be omitted and the top plate and the bottom plate may be in direct contact with each other. In this instance the thickness of the top and bottom plates may need to be increased to allow room for additional components that primarily reside between the two plates. These additional components are discussed below.

Although any type of three dimensional object may serve as a spacer between the top and bottom plates, the washer-like spacers **23** shown in FIG. 3 are preferred because they are easily removed and are adjustable when used in conjunction a set of locking pins **17**. Likewise, any attaching mechanism such as nuts and bolts, screws, etc., may be used to secure the positioning of the top plate **20** with respect to the bottom plate **22**, however, multiple locking pins, in conjunction with washer-like spacers, provide sufficient stability and desired adjustability.

Referring now to FIG. 4 and FIG. 5, the bottom plate **22** is situated beneath the top plate **20**. When the contact lens **16** is deblocked and falls toward the bottom plate **22** the deblocked lens **16** is received by a contact lens collector, generally indicated at **26**. In a preferred embodiment shown in FIG. 5, the bottom plate **22** possesses a plurality of contact lens collectors **26** retained within a plurality of bottom plate holes **25**. The contact lens collector **26** comprises a generally hemispherical structure **32** enclosed by an integrated flange **34**. The contact lens collector **26** is preferably made from a polymer and is molded to “snap-fit” within bottom plate hole **25** as generally indicated by the “tongue and groove” junction **38** shown in FIG. 5. The generally hemispherical structure **32** is convex and extends upward from the flange **34** to a point intermediate the top plate surface **19** and the bottom plate.

It is to be understood that numerous other orientations are possible for the bottom plate and the contact lens collector. For example, the contact lens collector could comprise a table-like structure rather than a hemispherical structure. Likewise, the bottom plate and the contact lens collector could be a single integrated unit. Furthermore, the generally hemispherical structure **32**, shown in a convex orientation in FIG. 5, could be concave to receive a contact lens from a base curve mold.

The generally hemispherical structure **32** shown in FIG. 5 preferably possesses several holes or perforations **36** for reducing the effective surface area of the hemispherical structure **32**.

The top plate **20** and the bottom plate **22** are separated after deblocking is completed. The bottom plate **22** and the deblocked contact lens **16** proceed to subsequent points in the manufacturing process.

After the initial observation that temperature reduction alone could deblock a contact lens, several more experiments were conducted to explore what effect, if any, this deblocking method had on a lens. These experiments proceeded as follows.

One hundred and fifty six (156) lenses with a Rx of -1.75 are manufactured according to Example B5 of U.S. Patent No. 5,760,100 and staged within their molds and plastic bags for approximately 25 days prior to mold separation. Upon separation, the lenses and the front curve molds to which they adhered are separated into three groups each containing 52 lenses: A (Example 1), B (Example 2), and C (Example 3), for further testing. No lenses are damaged due to mold separation.

#### EXAMPLE 1

(Prior Art)

The Group A lenses are deblocked using IPA deblocking techniques known in the art. Each lens successfully separates from its mold surface by bathing the lens in IPA. All lenses exhibit good clarity, sphericity, and flex.

#### EXAMPLE 2

The Group B lenses are deblocked using direct contact with liquid nitrogen (i.e. liquid nitrogen was applied directly to the lens). Each lens separates from its mold surface, taking an average of 9.8 seconds. All lenses deblocked by this technique exhibit good clarity, sphericity, and flex. Furthermore, the deblocking technique does not result in detrimental changes in Rx measurements, mechanical properties (modulus, maximum stress, maximum elongation, and thickness), ion permeability, or XPS.

#### EXAMPLE 3

The Group C lenses are deblocked using indirect contact with liquid nitrogen (i.e. liquid nitrogen was applied to the side of the front curve mold opposite the contact lens). Forty-seven out of the fifty-two lenses separate from the mold surface, taking an average of 16.5 seconds. The failure of the five lenses to separate may have been partially due to excess lens material in the mold. All lenses deblocked by this technique exhibit good clarity, sphericity, and flex. Furthermore, the deblocking technique does not result in detrimental changes in Rx measurements, mechanical properties (modulus, maximum stress, maximum elongation, and thickness), ion permeability, or XPS.

As stated previously, the invention is preferably practiced using polypropylene molds. Because polypropylene is a known insulator, the difference in time between Group A (direct contact; 9.8 s) and Group B (indirect contact; 16.5 s) is most likely due to differences in the cooling efficiency of the two cooling methods, as well as location for freezing. One of skill in the art will recognize that the placement of contact of the cryogenic material with the mold will affect the cooling efficiency. Only routine experimentation is necessary to determine the optimum placement. Currently, it is preferred to place the cryogenic material immediately above the contact lens in the mold as explained above with reference to FIG. 2.

The invention has been described in detail, with reference to certain preferred embodiments, in order to enable the reader to practice the invention without undue experimentation. However, a person having ordinary skill in the art will readily recognize that many of the components and parameters may be varied or modified to a certain extent without departing from the scope and spirit of the invention. Furthermore, titles, headings, or the like are provided to enhance the reader's comprehension of this document, and should not be read as limiting the scope of the present invention. Accordingly, only the following claims and reasonable extensions and equivalents define the intellectual property rights to the invention.

## CLAIMS

What is claimed is:

1. A method for extracting a polymeric contact lens from a mold, the method comprising:

- 5        lowering the temperature of the contact lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens, and  
          thereafter removing the lens from the mold.

10    2. The method of claim 1 wherein said step of lowering the temperature of the contact lens comprises substantially reducing the molecular mobility of the contact lens polymer using a cryogenic substance.

15    3. The method of claim 2 wherein the step of substantially reducing the molecular mobility of the contact lens comprises directly contacting the contact lens with a cryogenic substance.

20    4. The method of claim 3 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.

5. The method of claim 2 wherein the step of substantially reducing the molecular mobility of the contact lens comprises contacting the mold with a cryogenic substance while the lens is in contact therewith.

25    6. The method of claim 5 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.

7. The method of claim 1 wherein the contact lens comprises a siloxane-containing polymer.

30

8. A method for extracting a silicon containing polymeric contact lens from a mold, the method comprising:

bringing the lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens,  
5 separating the lens from the mold, and  
recovering the lens.

9. A method according to claim 8 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.  
10

10. A method according to claim 8 wherein the step of separating the lens from the mold comprises lowering the temperature of the lens to a temperature at which the lens will release from the mold without the application of external force to the lens.  
15

11. A method for extracting a silicon containing polymeric contact lens from a mold, the method comprising:

bringing the mold into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens,  
20 separating the lens from the mold, and  
recovering the lens.

12. A method according to claim 11 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.  
25

13. A method according to claim 11 wherein the step of causing separation of the lens from the mold comprises lowering the temperature of the lens to a temperature at which the lens will release from the mold without the application of external force to the lens.  
30



14. A method for extracting a silicon containing polymeric contact lens from a mold, the method comprising:

orienting a contact lens bearing mold upon a carrier such that the contact lens may fall from the mold;

5       situating a contact lens collector so as to collect a falling contact lens;  
causing the mold to come into intimate contact with a cryogenic substance;  
causing separation of the lens from the mold; and  
collecting the lens.

10   15. A method according to claim 14 wherein the step of causing separation of the lens from the mold comprises causing the mold to come into intimate contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where the lens will automatically separate from the mold and fall to the lens collector.

15   16. A method according to claim 15 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.

20   17. A method for manufacturing a silicon containing polymeric contact lens from a mold, the method comprising:

bringing two mold halves together to form a lens mold;

filling the mold with an uncured polymer;

curing the polymer in the mold;

separating the mold halves from one another;

25       bringing the mold half bearing the contact lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold half to a point where removing the lens will not damage the lens;

separating the lens from the mold half, and

30       recovering the lens.

18. A method according to claim 17 wherein the cryogenic substance is selected from the group consisting of liquid nitrogen, liquid helium and solid carbon dioxide.

19. A method according to claim 18 wherein the step of causing separation of the lens from the mold half comprises bringing the mold half bearing the lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold half to a point where the lens will fall from the mold half when the mold half is oriented above the lens.

20. An apparatus for deblocking and collecting contact lenses formed of hydrophilic polymers that tend to adhere to mold surfaces, said apparatus comprising:

a contact lens mold; and

means for cooling said lens mold to a temperature at which a contact lens on said lens mold will release from said mold without damage to the contact lens.

21. A deblocking apparatus according to claim 20 wherein said cooling means comprises a reservoir in said lens mold for receiving a cryogen therein.

22. A deblocking apparatus according to claim 20 and further comprising a lens collector for receiving a contact lens that has been released from said lens mold.

23. A deblocking apparatus according to claim 22 and further comprising means for aligning said lens mold with said lens collector so that lenses released from said lens mold transfer properly to said lens collector.

24. A deblocking apparatus according to claim 23 wherein said aligning means comprises at least one pair of retaining mechanisms situated parallel and opposite to one another.

25. A deblocking apparatus according to claim 24 wherein said pair of parallel and opposite retaining mechanisms comprises at least two plates, with one of said plates having a lens collector and the other of said plates having a lens mold.

5 26. A deblocking apparatus according to claim 25 wherein said lens mold plate is situated above said lens collector plate.

27. An apparatus for deblocking and collecting contact lenses, the apparatus comprising:

10 a top plate having at least one top plate hole for receiving a contact lens mold bearing a contact lens, and

a bottom plate having at least one lens collector for receiving said contact lens, said lens collector being in axial alignment with said top plate hole.

15 28. An apparatus according to claim 27 wherein said bottom plate further comprises a bottom plate hole with said contact lens collector being removably positioned in said hole.

29. The apparatus of claim 28 wherein said contact lens collector is a generally hemispherical structure having an inner surface and an outer surface, said generally hemispherical structure being oriented with the apex of said generally hemispherical structure extending toward said top plate.

30. A deblocking apparatus according to claim 29 wherein said generally hemispherical structure possesses a plurality of openings that reduce the outer surface area of said generally hemispherical structure.

31. A deblocking apparatus according to claim 30 wherein said generally hemispherical structure is formed from a polymer and snap fits within said bottom plate hole.

32. A deblocking apparatus according to claim 31 wherein the outer surface of said generally hemispherical structure possesses raised protrusions for further reducing the effective outer surface area of said generally hemispherical structure.

5 33. A deblocking apparatus according to claim 27 wherein said top plate further comprises a structure for securing the positioning of said received contact lens mold.

34. A deblocking apparatus according to claim 33 wherein said securing structure comprises a pair of flexible tabs on said plate opposite from one another along the perimeter  
10 of said top plate hole for being urged against the mold when a mold is in said top plate hole to thereby maintain a lens mold in said top plate hole.

35. An apparatus for deblocking and collecting contact lenses, said apparatus comprising:

15 a top plate and a bottom plate;  
said top plate having respective top and bottom surfaces and a plurality of top plate holes for providing fluid communication between said top and bottom top plate surfaces, said top plate holes being of sufficient diameter to receive a front curve contact lens mold; and  
20 said bottom plate having a plurality of contact lens collectors, said contact lens collectors being removably retained within a plurality of bottom plate holes; and  
said plates being aligned with said bottom plate holes in axial alignment with said top plate holes.

25 36. A deblocking apparatus according to claim 35 further comprising at least one spacing device situated between said top plate and said bottom plate.

37. A deblocking apparatus according to claim 35 wherein said top plate further comprises at least one retaining device to secure the positioning of front curve lens molds  
30 that are placed in said top plate.

38. A deblocking apparatus according to claim 35 wherein said contact lens collector is a generally disklike structure having an outer diameter and an inner diameter defining a flange, said flange enclosing a generally hemispherical portion extending from said flange to a point intermediate said top plate top surface and said bottom plate.

5

39. A deblocking apparatus according to claim 38 wherein said generally hemispherical portion possesses an inner surface and an outer surface and a plurality of openings that effectively reduce the outer surface area of said generally hemispherical portion.

10

40. A deblocking apparatus according to claim 39 wherein said generally hemispherical portion is formed from a polymer and snap fits within said bottom plate hole.

15

41. A deblocking apparatus according to claim 39 wherein the outer surface of said generally hemispherical portion possesses raised protrusions to further reduce the effective outer surface area of said generally hemispherical portion.

20

42. An apparatus for deblocking and collecting contact lenses, said apparatus comprising:

a top plate and a bottom plate separated by at least one spacer;

said top plate having respective top and bottom surfaces and a plurality of top plate holes for providing fluid communication between said top and bottom surfaces, said top plate holes being of sufficient diameter to receive a front curve contact lens mold bearing a contact lens; and

25

said top plate further having a retaining device for securing the positioning of front curve lens molds that are received by said top plate, said retaining device comprising at least two flexible tabs oriented perpendicular to said top plate top surface; and

30

said bottom plate having a plurality of lens collectors, said lens collectors being generally hemispherical, perforated, polymeric, and oriented such that the apex of said generally hemispherical lens collector extends towards said top plate, said generally

hemispherical lens collector being removably retained within a plurality of bottom plate holes and;

said plates being aligned with said bottom plate holes being in axial alignment with said top plate holes.

5

**ABSTRACT**

A method and apparatus for removing a polymeric contact lens from a mold comprising lowering the temperature of the contact lens with a cryogenic material, such as liquid nitrogen, to a temperature and for a time sufficient for the lens to release from  
5 the mold without the application of external forces.

1. $\alpha$ and $\beta$ are given by	
$\alpha = 1$	$\beta = 1$
$\alpha = 2$	$\beta = 2$
$\alpha = 3$	$\beta = 3$
$\alpha = 4$	$\beta = 4$
$\alpha = 5$	$\beta = 5$
$\alpha = 6$	$\beta = 6$
$\alpha = 7$	$\beta = 7$
$\alpha = 8$	$\beta = 8$
$\alpha = 9$	$\beta = 9$
$\alpha = 10$	$\beta = 10$
$\alpha = 11$	$\beta = 11$
$\alpha = 12$	$\beta = 12$
$\alpha = 13$	$\beta = 13$
$\alpha = 14$	$\beta = 14$
$\alpha = 15$	$\beta = 15$
$\alpha = 16$	$\beta = 16$
$\alpha = 17$	$\beta = 17$
$\alpha = 18$	$\beta = 18$
$\alpha = 19$	$\beta = 19$
$\alpha = 20$	$\beta = 20$
$\alpha = 21$	$\beta = 21$
$\alpha = 22$	$\beta = 22$
$\alpha = 23$	$\beta = 23$
$\alpha = 24$	$\beta = 24$
$\alpha = 25$	$\beta = 25$
$\alpha = 26$	$\beta = 26$
$\alpha = 27$	$\beta = 27$
$\alpha = 28$	$\beta = 28$
$\alpha = 29$	$\beta = 29$
$\alpha = 30$	$\beta = 30$
$\alpha = 31$	$\beta = 31$
$\alpha = 32$	$\beta = 32$
$\alpha = 33$	$\beta = 33$
$\alpha = 34$	$\beta = 34$
$\alpha = 35$	$\beta = 35$
$\alpha = 36$	$\beta = 36$
$\alpha = 37$	$\beta = 37$
$\alpha = 38$	$\beta = 38$
$\alpha = 39$	$\beta = 39$
$\alpha = 40$	$\beta = 40$
$\alpha = 41$	$\beta = 41$
$\alpha = 42$	$\beta = 42$
$\alpha = 43$	$\beta = 43$
$\alpha = 44$	$\beta = 44$
$\alpha = 45$	$\beta = 45$
$\alpha = 46$	$\beta = 46$
$\alpha = 47$	$\beta = 47$
$\alpha = 48$	$\beta = 48$
$\alpha = 49$	$\beta = 49$
$\alpha = 50$	$\beta = 50$
$\alpha = 51$	$\beta = 51$
$\alpha = 52$	$\beta = 52$
$\alpha = 53$	$\beta = 53$
$\alpha = 54$	$\beta = 54$
$\alpha = 55$	$\beta = 55$
$\alpha = 56$	$\beta = 56$
$\alpha = 57$	$\beta = 57$
$\alpha = 58$	$\beta = 58$
$\alpha = 59$	$\beta = 59$
$\alpha = 60$	$\beta = 60$
$\alpha = 61$	$\beta = 61$
$\alpha = 62$	$\beta = 62$
$\alpha = 63$	$\beta = 63$
$\alpha = 64$	$\beta = 64$
$\alpha = 65$	$\beta = 65$
$\alpha = 66$	$\beta = 66$
$\alpha = 67$	$\beta = 67$
$\alpha = 68$	$\beta = 68$
$\alpha = 69$	$\beta = 69$
$\alpha = 70$	$\beta = 70$
$\alpha = 71$	$\beta = 71$
$\alpha = 72$	$\beta = 72$
$\alpha = 73$	$\beta = 73$
$\alpha = 74$	$\beta = 74$
$\alpha = 75$	$\beta = 75$
$\alpha = 76$	$\beta = 76$
$\alpha = 77$	$\beta = 77$
$\alpha = 78$	$\beta = 78$
$\alpha = 79$	$\beta = 79$
$\alpha = 80$	$\beta = 80$
$\alpha = 81$	$\beta = 81$
$\alpha = 82$	$\beta = 82$
$\alpha = 83$	$\beta = 83$
$\alpha = 84$	$\beta = 84$
$\alpha = 85$	$\beta = 85$
$\alpha = 86$	$\beta = 86$
$\alpha = 87$	$\beta = 87$
$\alpha = 88$	$\beta = 88$
$\alpha = 89$	$\beta = 89$
$\alpha = 90$	$\beta = 90$
$\alpha = 91$	$\beta = 91$
$\alpha = 92$	$\beta = 92$
$\alpha = 93$	$\beta = 93$
$\alpha = 94$	$\beta = 94$
$\alpha = 95$	$\beta = 95$
$\alpha = 96$	$\beta = 96$
$\alpha = 97$	$\beta = 97$
$\alpha = 98$	$\beta = 98$
$\alpha = 99$	$\beta = 99$
$\alpha = 100$	$\beta = 100$

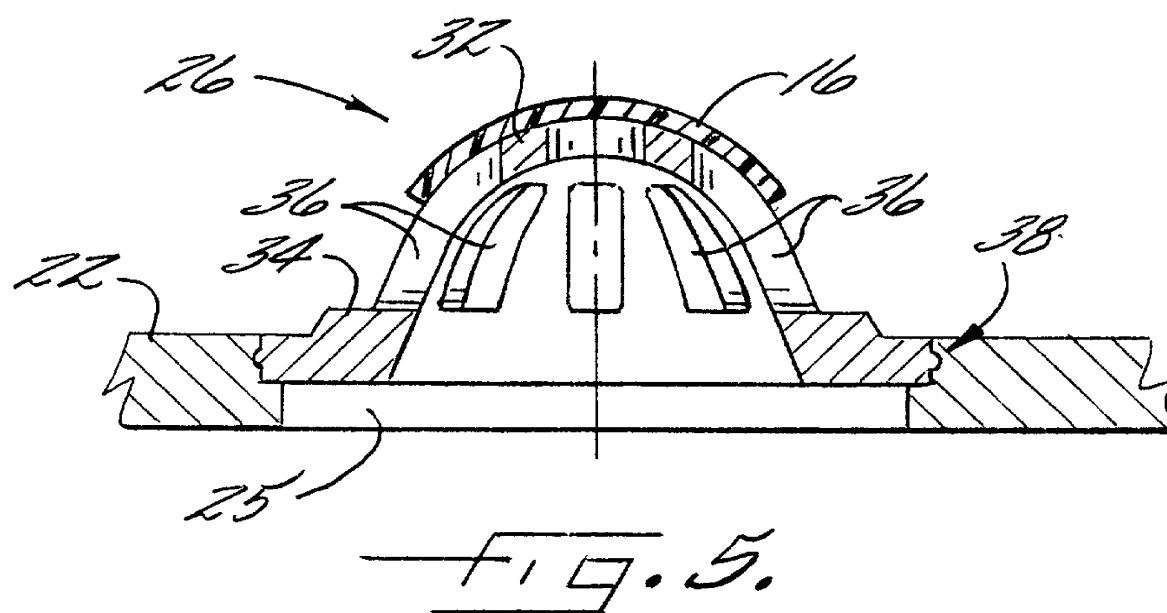
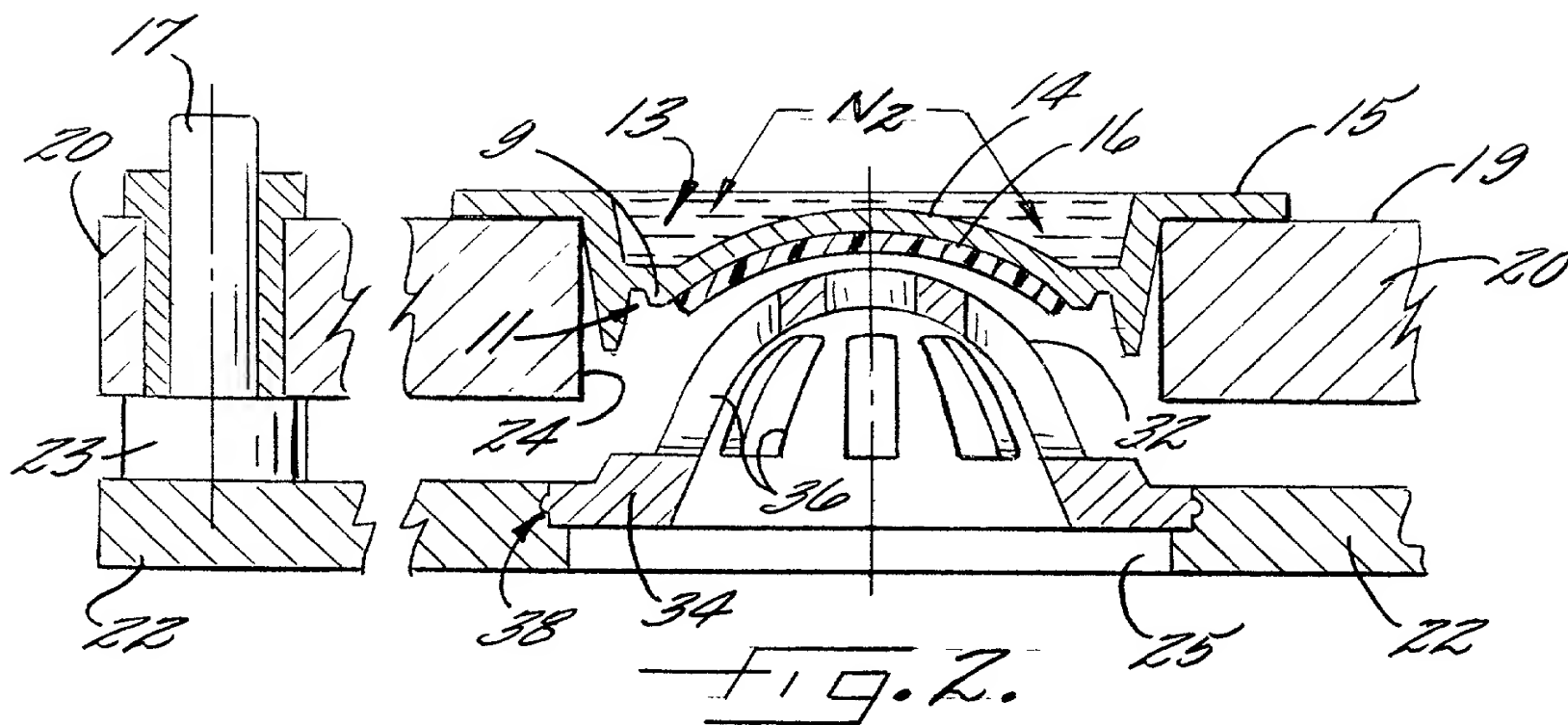
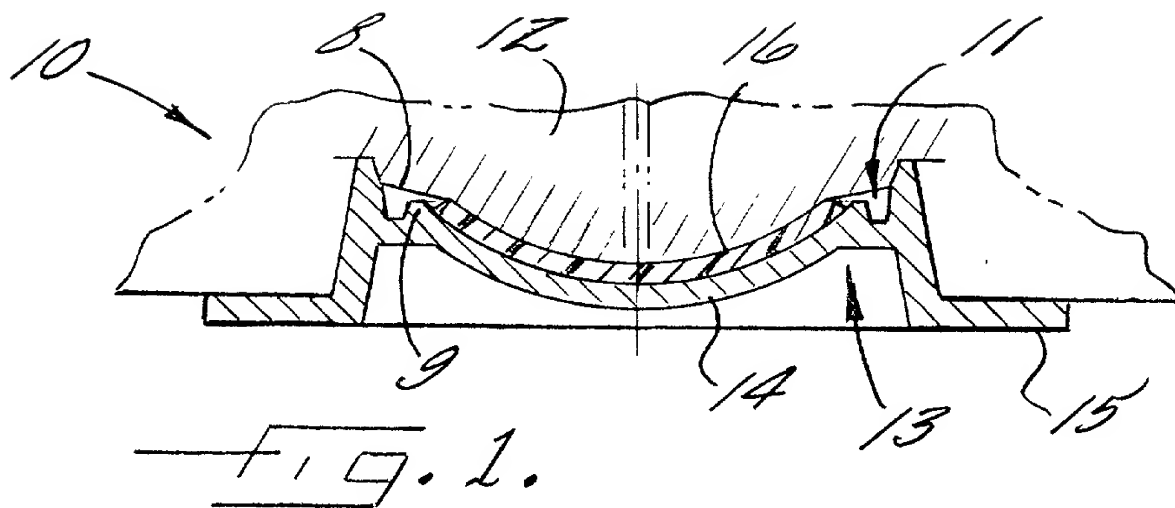




Fig. 4.

**DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION**

☒ Original      ☐ Supplemental      ☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled DEBLOCKING CONTACT LENSES

the specification of which

☒ is attached hereto.

☐ was filed on \_\_\_\_\_, 19\_\_\_\_ as Application No.

and, if these brackets contain an X ☐, was amended on

☐ was filed as Patent Cooperation Treaty international Application No. \_\_\_\_\_ on \_\_\_\_\_, 19\_\_\_\_, if these brackets contain an X ☐, entered the national stage in the United States and was accorded Application No. 0 / \_\_\_\_\_ and, if these brackets contain an X ☐, was amended, subsequent to entry into the national stage, on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose all information which is known by me to be material to the patentability of this application as defined in 37 C.F.R. §1.56.

I hereby claim the benefit under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate listed below and under 35 U.S.C. §365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent or inventor's certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

<u>Country, Region</u> <u>or P.C.T.</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Priority</u> <u>Claimed</u>
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

_____	[ ] Yes [ ] No
_____	[ ] Yes [ ] No
_____	[ ] Yes [ ] No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

<u>Application No.</u>	<u>Filing Date</u>
_____	_____
_____	_____
_____	_____

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) listed below and under 35 U.S.C. §365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in said prior application(s) in the manner required by the first paragraph of 35 U.S.C. §112, I acknowledge my duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date(s) of the prior application(s) and the national or Patent Cooperation Treaty international filing date of this application:

<u>United States</u> <u>Application No.</u>	<u>United States</u> <u>Filing Date</u>	<u>Status (Pending,</u> <u>Abandoned or</u> <u>U. S. Patent No.)</u>	<u>International</u> <u>Applicaton No.</u> <u>and Filing Date</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

I hereby appoint the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If these brackets contain an X [ ], I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from the Patents and Trademarks Division of Novartis Services AG., Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please address all communications to Michael W. Glynn, Novartis Corporation, Patent and Trademark Department, 564 Morris Avenue, Summit, NJ 07901-1027.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sole inventor or

first joint inventor: Full Name : Ellen Marie Ajello

Signature : Ellen Marie Ajello  
Date : 10-22-99  
Citizenship : United States  
Residence : 1683 Springbrook Drive  
Decatur, Georgia 30033  
P.O. Address : 1683 Springbrook Drive  
Decatur, Georgia 30033

Second joint inventor  
if any Full Name

: Michael Nelson Wilde

Signature : [Signature]  
Date : 10-22-99  
Citizenship : United States  
Residence : 4225 Abington Walk  
Kennesaw, Georgia 30144  
P.O. Address : 4225 Abington Walk  
Kennesaw, Georgia 30144

Third joint inventor,  
if any:

Full Name : Yasuo Matsuzawa

Signature : [Signature]  
Date : 10/26/99  
Citizenship : Japanese  
Residence : 10450 Turner Road  
Roswell, Georgia 30076  
P.O. Address : 10450 Turner Road  
Roswell, Georgia 30076